

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Dalfampridine
Dalfampridinum
Dalfampridine
Dalfampridine
Dalfampridin

N° CAS: 504-24-5

N° EC: 207-987-9

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 2	H300
Skin Irrit. 2	H315
Eye Irrit. 2	H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



DALFAMPRIDINUM

H300	Fatal if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Precautionary statements:	
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P309+P310	IF exposed or if you feel unwell: immediately call a POISON CENTER or doctor/physician.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Dalfampridine
IUPAC name:	Pyridin-4-amine
Synonyms:	4-Aminopyridine Pymadine
N° CAS:	504-24-5
N° EC:	207-987-9
Molecular Formula:	C ₅ H ₆ N ₂
Content:	98.0 per cent to 102.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Remove from exposure area to fresh air immediately. If breathing has stopped, perform artificial respiration. Keep person warm and at rest. Treat symptomatically and supportively. Get medical attention immediately.
After skin contact:	Remove contaminated clothing and shoes immediately. Wash affected area with soap or mild detergent and large amounts of water until no evidence of chemical remains (approximately 15-20 minutes). Get medical attention immediately.
After eye contact:	Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (approximately 15-20 minutes). Get medical attention immediately.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



After ingestion:

If swallowed, wash out mouth with water, provided the person is conscious. Treat symptomatically and supportively. Get medical attention immediately. If vomiting occurs, keep head lower than hips to prevent aspiration.

4.2 Most important symptoms and effects, both acute and delayed

For symptoms and effects, see section 11.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:

Chemical powder, carbon dioxide, spray water and chemical foam.
In case of a larger fire, use spray water or foam.

Unsuitable extinguishing media:

Not available.

5.2 Special hazards arising from the substance/mixture

Slight fire hazard when exposed to heat or flame. Dust-air mixtures may ignite or explode. Thermal decomposition products may include carbon monoxide, carbon dioxide and nitrogen oxides.

5.3 Advice for firefighters

Surrounding fires:

Remove container from the endangered area if it is possible without danger. Don't use high pressure water jets, in order to avoid scattering material. Dispose of water used to extinguish fire. Avoid inhaling vapours, keep downwind.

Protection against fire:

Not available.

Hazardous combustion products:

Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective clothing, gloves and goggles. Evacuate area. Remove any ignition source.

For emergency responders

Wear protective clothing, gloves and goggles. Evacuate area. Remove any ignition source.

6.2 Environmental precautions

Don't throw this substance in sewer or ground water.

6.3 Methods and material for containment and cleaning up

Pick up without raising dust. Keep contaminated material in tightly closed containers. Wash with water.

6.4 Reference to other sections

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Handling in ventilated area; avoid raising dust. Ensure good ventilation and local exhaust.
Personal protection:	Wear personal protective equipment (refer to section 8) before handling substance. Avoid contact with skin and eyes. Avoid breathing dust.
Technical protective measures:	Wash thoroughly after handling.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in a well-closed container.
Conditions for safe storage, including any incompatibilities:	Keep at room temperature.
Storage – away from:	Store out of sunlight.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Supply places with exhaust ventilation system. In presence of explosive concentrations of dust, vapour or fumes, the ventilation system must be explosion proof.

Individual protection measures

Eye/face protection:	Employee must wear splash-proof or dust-resistant safety goggles to prevent the substance getting into eyes. Specific equipment must be available at the workplace: where contact between workers and the substance is possible, the employer must have safety shower and eye bath available within the immediate work area for emergency use.
Skin protection:	Wear suitable protective apparatus and protective clothing to prevent contact with the substance.
Hand protection:	Wear heavy rubber gloves.
Respiratory protection:	The following respirators are recommended based on information found in the physical data, toxicity and health effects sections. They are ranked in order from minimum to maximum respiratory protection. The specific respirator selected must be based on contamination levels found in the workplace, on the specific operation, it must not exceed the working limits of the respirator and must be jointly approved

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA).

Any dust or mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

Any powered air-purifying respirator with a dust or mist filter.

Any powered air-purifying respirator with a high-efficiency particulate filter.

Any type 'C' supplied air respirator operated in the pressure-demand or other positive pressure or continuous-flow mode.

Any self-contained breathing apparatus.

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Solid, beige.
Odour:	Unpleasant.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	157 °C – 160 °C
Initial boiling point:	274 °C
Boiling range:	Not available.
Flash point:	156 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	2.09×10^{-4} mm Hg at 20 °C
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Not available.
Solubility in water:	83 g/l (20 °C)
Partition coefficient (n-octanol/water):	0.32
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 94.11

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Risk of dust explosion.

10.2 Chemical stability

Sensitivity to light.

10.3 Possibility of hazardous reactions

Oxidising agents, acid halides, acid anhydrides, acids.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Thermal decomposition products may include carbon monoxide, carbon dioxide and nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD50 (rat): 21 mg/kg

Skin corrosion/irritation: Causes skin irritation.

Serious eye damage/irritation: Causes serious eye irritation.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: RTECS NO: US1750000

Target organs data: systemic effects: dizziness, muscular symptoms, rise in blood pressure, confusion, unconsciousness, coma.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	Causes skin irritation.
Inhalation:	Not available.
Ingestion:	Fatal if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish LC50 (96h): 2.8 (*Lepomis macrochirus*)
EC 50 (48h): 3.2 (*Daphnia magna*)

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Low Pow: 0.32.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal in accordance with international, national and local regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 2671
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Aminopyridines
IATA/ICAO (Air) :

14.3 Transport hazard class(es)

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 18/03/2022

Revision: 24/07/2024

Version: 01



ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : 6.1

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : II

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.6 Special precautions for user

Warning: Toxic substances.
Danger code (Kemler): 60

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Risk phrases:

R28 Very toxic if swallowed.
R36 Irritating to eyes.
R38 Irritating to skin.

Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 After contact with skin, wash immediately with plenty of soap and water.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS: Chemical Abstracts Service (division of the American Chemical Society)
EC (number): European Community (number)

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

DALFAMPRIDINUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 18/03/2022

Revision: 24/07/2024

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IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department

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